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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,578	05/15/2006	Marie-Claire Janailhac	JANAILHAC1	6899

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EXAMINER

MI, QIUWEN

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,578	Applicant(s) JANAILHAC ET AL.	
	Examiner Qiuwen Mi	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment in the reply filed on 11/30/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

Claims Pending

Claims 4-6 are cancelled. Claims 1-3, and 7-18 are pending. Claims 8-15 are withdrawn as they are directed toward a non-elected invention groups or species. Claims 1-3, 7, and 16-18 are examined on the merits.

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Amended Claim 1 recites "said extract comprising protein in a mass ratio comprised between 0.005% and 1% m/m, vitamin B12 in a mass ratio comprised between 0.003% and 0.05% m/m, lysine in a mass ratio comprised between 0.02% and 3% m/m, proline in a mass ratio comprised between 0.15% and 2.5% m/m, serine in a mass ratio comprised between 0.15% and 2.5% m/m" in the claim. However, the specification fails to provide any support regarding

the description of the claimed components in the extract, let alone the amounts. Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the "a second delivery system" in the invention. Thus, the subject matter of "a second delivery system" is a new matter that needs to be cancelled.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, 1st paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anchevskii et al (RU 2182820) in view of Li (Hydrobiologia 438: 99-105, 2000), and further in view of Patterson et al (US 5,439,933), as evidenced by Shelest et al (Feed hydrolysate from blue-green algae, Svinovodstvo, Moscow, 10: 28-29, 1983)*, Feoktistova (The effect of cobalt on the number of planktonic blue-green algae and on their synthesis of vitamin B12 referat,

Byul. Inst. Biol. Vodokhran-ilisch. Akad. Nauk SSSR. pp. 3-6, 1961)*, and Baudouin et al (FR 2796556A)*.

Anchevskii et al disclose a cosmetic cream (topical, emulsions, on skin) (contains cosmetically acceptable carrier, such as water) comprising 0.5-1.5% powder of blue-green algae (the same as *Aphanizomenon flos-aquae*).

As evidenced by Shelest et al, blue-green algae contains protein, lysine, serine, and proline (see Abstract).

As evidenced by Feoktistova, blue-green algae synthesizes vitamin B12 (see Abstract).

As evidenced by Baudouin et al, extract of blue-green algae is useful in cosmetic and compositions in combating skin aging.

Anchevskii et al do not disclose the specific variety of *Aphanizomenon flos-aquae* var. *flos-aquae* in a control released composition.

Li teaches the taxonomic of cyanobacteria genus *Aphanizomenon* and species *Aphanizomenon flos-aquae* var. *flos-aquae*. Li indicates that *Aphanizomenon flos-aquae* var. *flos-aquae* in fish ponds (as aqueous solution) are used as a health food supplement by several hundred thousand consumers in Northern America (see entire document including, e.g., page 102, Table 1; page 104, right column, second paragraph).

Patterson et al disclose a new compound isolated from blue-green algae (see Abstract) used in topical applications for antifungal activity (col 9, lines 5-10). Patterson et al also teach

compound isolated from blue-green algae can be used in the sustained released formulations (a type of controlled release) (col 8, lines 55-60).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the species *Aphanizomenon flos-aquae* var. *flos-aquae* of Li and the sustained released formulations of Patterson et al in the invention of Anchevskii et al for the following reasons:

It is clear from Li that species *Aphanizomenon flos-aquae* var. *flos-aquae* is available in fish pond, and its quantity is sufficient enough to supply as large as several hundred thousand of consumers in Northern America. It is also clear from Li that species *Aphanizomenon flos-aquae* var. *flos-aquae* is not only non-toxic but also beneficial as it is used as a health food supplement. Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the easily obtained nontoxic species *Aphanizomenon flos-aquae* var. *flos-aquae* of Li in the genus of *Aphanizomenon flos-aquae* for topical application as taught by Anchevskii et al. As evidenced by Shelest et al and Feoktistova, blue-green algae contains the claimed protein, lysine, serine, proline, vitamin B12, as further evidenced by Baudouin et al, extract of blue-green algae is useful in cosmetic and compositions in combating skin aging.

It is also clear from Patterson et al that the compound isolated from blue-green algae has antifungal activity when used topically, and sustained release formulation as taught by Patterson et al is well known in the art for prolonged effect. Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the sustained released formulation of Patterson et al to enhance the effect of cosmetic cream of Anchevskii et al since

both the inventions use the extract/compound isolated from genus blue-green algae. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of protein, lysine, serine, praline, and vitamin B12 in the extract of *Aphanizomenon flos-aquae* var. *flos-aquae*) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. It is deemed that the product by process claim in claim 1, using cellulases, pectinases, and gucanases to break down cell wall to release cytoplasm content of algae does not materially different with the blue-green algae extract containing the claimed components.

Since all of the invention yielded beneficial results in cosmetic and food industry, one of ordinary skill in the art would have been motivated to make the modifications.

Claims 1-3, 7, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anchevskii et al (RU 2182820) in view of Li (Hydrobiologia 438: 99-105, 2000) and Zecchino et al (US 5,008,100), and further in view of Patterson et al (US 5,439,933) and Grollier (US 4,804,531), as evidenced by Shelest et al (Feed hydrolysate from blue-green algae, Svinovodstvo, Moscow, 10: 28-29, 1983)*, Feoktistova (The effect of cobalt on the number of

planktonic blue-green algae and on their synthesis of vitamin B12 referat, Byul. Inst. Biol. Vodokhran-ilisch. Akad. Nauk SSSR. pp. 3-6, 1961)*, and Baudouin et al (FR 2796556A)*.

Anchevskii et al disclose a cosmetic cream (topical, emulsions, on skin) (contains cosmetically acceptable carrier, such as water) comprising 0.5-1.5% powders of blue-green algae (the same as *Aphanizomenon flos-aquae*).

As evidenced by Shelest et al, blue-green algae contains protein, lysine, serine, and proline (see Abstract).

As evidenced by Feoktistova, blue-green algae synthesis vitamin B12 (see Abstract).

As evidenced by Baudouin et al, extract of blue-green algae is useful in cosmetic and compositions in combating skin aging.

Anchevskii et al do not disclose the specific variety of *Aphanizomenon flos-aquae* var. *flos-aquae* in sorbitol and water, in a control-released, after-sun care composition.

Li teaches the taxonomic of cyanobacteria genus *Aphanizomenon* and species *Aphanizomenon flos-aquae* var. *flos-aquae*. Li indicates that *Aphanizomenon flos-aquae* var. *flos-aquae* in fish pound (as aqueous solution) are used as a health food supplement by several hundred thousand consumers in Northern America (see entire document including, e.g., page 102, Table 1; page 104, right column, second paragraph).

Zecchino et al disclose a stable oil-in-water skin compatible sunscreen cream (see Abstract) comprising deionized water, carbomer/Carbopol, disodium EDTA, silicon fluid, methylparaben, triethanolamine, ethylparaben (antimicrobial preservative) and fragrance (perfume) (cols 7&8, Example 2). Zecchino et al also teach that the composition has a greater sun protection factor than other compositions which have the same levels of conventional sunscreen agents (col 3, lines 33-37).

Patterson et al disclose a new compound isolated from blue-green algae (see Abstract) used in topical applications for antifungal activity (col 9, lines 5-10). Patterson et al also teach compound isolated from blue-green algae can be used in the sustained released formulations (the same as controlled release) (col 8, lines 55-60).

Grollier discloses a sunscreen cream comprising sorbitol (col 8, Example 7). Grollier also teaches that the composition increases the protection index of the said screening composition, and protects the human epidermis against ultraviolet radiation (col 1, lines 28-32).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the species *Aphanizomenon flos-aquae* var. *flos-aquae* of Li, the sunscreen creams from Zecchino et al and Grollier, and the sustained released formulations of Patterson et al in the invention of Anchevskii et al for the following reasons: It is clear from Li that species *Aphanizomenon flos-aquae* var. *flos-aquae* is available in fish pond, and its quantity is sufficient enough to supply as large as several hundred thousand of

consumers in Northern America. It is also clear from Li that species *Aphanizomenon flos-aquae* var. *flos-aquae* is not only non-toxic but also beneficial as it is used as a health food supplement. Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the easily obtained nontoxic species *Aphanizomenon flos-aquae* var. *flos-aquae* of Li in the genus of *Aphanizomenon flos-aquae* for topical application as taught by Anchevskii et al. As evidenced by Shelest et al and Feoktistova, blue-green algae contains the claimed protein, lysine, serine, proline, vitamin B12, as further evidenced by Baudouin et al, extract of blue-green algae is useful in cosmetic and compositions in combating skin aging.

It is also clear from Zecchino et al that the sunscreen cream is stable, skin compatible, and has a greater sun protection factor than other compositions, therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the sunscreen cream composition as taught by Zecchino et al in the invention of Anchevskii et al to achieve the stability and greater sun protection.

It is also clear from Grollier that the sunscreen cream increases the protection index of the said screening composition, and protects the human epidermis against ultraviolet radiation therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the sunscreen cream composition as taught by Grollier in the invention of Anchevskii et al to achieve the stability and greater sun protection.

It is further clear from Patterson et al that the compound isolated from blue-green algae has antifungal activity when used topically, and sustained release formulation as taught by

Patterson et al is well known in the art for prolonged effect. Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the sustained released formulation of Patterson et al to enhance the effect of cosmetic cream of Anchevskii et al since both the inventions use the extract/compound isolated from genus blue-green algae.

Since all of the invention yielded beneficial results in cosmetic and food industry, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of protein, lysine, serine, praline, and vitamin B12 in the extract of *Aphanizomenon flos-aquae* var. *flos-aquae*, or an appropriate salt of EDTA or appropriate type of extract of *Aphanizomenon flos-aquae* var. *flos-aquae*, such as, sorbitol and water) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. It is deemed that the product by process claim in claim 1, using cellulases, pectinases, and gucanases to break down cell wall to release cytoplasm content of algae does not materially different with the blue-green algae extract containing the claimed components.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Answer to Applicant's Argument

Applicant argues that topically usable composition was not considered as possible due to the low level of solubilization of the dried algae, its strong coloration, its strong smell and the lack of stability of its biochemical compounds (page 12, 3rd paragraph). Applicant's argument is moot in light of the new reference of Baudouin et al, wherein the extract of blue-green algae is used successfully in cosmetic and compositions in combating skin aging.

Applicant also argues that Anchevskii et al does not deal with the problems raised in the applicant's specification which render impossible to incorporate a dried *Aphanizomenon-flos-aquae* var. *flos-aquae* in a cosmetic which is to be applied topically. It is noted that the features upon which applicant relies (i.e., solubility,) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that Li does not state that bacteria could be used as topic cosmetic (page 13, 3rd paragraph), and Patterson et al do not concern *Aphanizomenon-flos-aquae* var. *flos-aquae* (page 13, last paragraph). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the antifungal product in Patterson et al are usually considered as having a certain toxicity which is not compatible with the use of *Aphanizomenon-flos-aquae* var. *flos-aquae* by Li as healthy food (page 13, last paragraph). This argument has no bases. Since *Aphanizomenon-flos-aquae* var. *flos-aquae* is used as healthy food by Li, it is assumed to be safe when used topically together with the antifungal compound from Patterson et al. Examiner does not take the position of eating any antifungal compound as healthy food. Thus the argument is irrelevant.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Qiuwen Mi

/Patricia Leith/

Primary Examiner, Art Unit 1655

February 12, 2008